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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/053,299 | 01/17/2002 | Michael A. Zasloff | MZ 100 | 5008 |

7590 12/03/2003

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| EXAMINER |
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SHEIKH, HUMERA N

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,299

Applicant(s)

ZASLOFF ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 17, 19-24, 26-30, 33 and 35-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 25, 31, 32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Application

Receipt of the Response to Election/Restriction Requirement filed 09/08/03 is acknowledged.

Claims 17, 19-24, 26-30, 33 and 35-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4. The traversal is on the ground(s) that the claims generic to species (a) through (h) are in fact allowable. This is not found persuasive because the instant claims were not found to be allowable in view of the prior art of record.

The requirement is still deemed proper and is therefore made FINAL.

Claim 20 has been withdrawn because it is dependent upon non-elected subject matter (claim 19).

Claims 1-16, 18, 25, 31, 32 and 34 are pending. Claims 17, 19-24, 26-30, 33 and 35-40 have been withdrawn. Claims 1-16, 18, 25, 31, 32 and 34 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16, 18, 25, 31, 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundstrom *et al.* (US Pat. No. 6,388,056 B1).

Sundstrom *et al.* teach compounds and methods for the prevention and treatment of microbial infection of a mammalian host through the administration of substrates for transglutaminases or antibodies against such substrates that inhibit the transglutaminase-mediated interaction with the mammalian host. These compounds and methods may be used in the identification, prevention or treatment of microbial infection of mammalian hosts, such as, for example,

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immunocompromised or immunosuppressed humans. (see Abstract and col. 1, lines 1-15). The polypeptides used in the invention act as substrates for mammalian transglutaminases and include amino acids of *isoleucine*, serine and glutamine, whereby the amino acid residues are preferred to be in the L isomeric form, however the D isomeric form may also be used (col. 9, line 5 – col. 10, line 11).

Sundstrom teach that during initial infection, the interaction of a microorganism with its mammalian host can include attachment or adhesion to the host cell surface, invasion of host cells, and elaboration of toxins. In certain instances, this interaction can be nonspecific. In others, such microbial interaction involves the specific binding of the microorganism to a particular receptor or receptor complex expressed on the host cell surface (col. 1, lines 20-32).

According to Sundstrom, the antibody is capable of inhibiting the interaction of a microorganism with a mammalian cell. The mammalian cell is a human cell, preferably an epithelial cell, more preferably a mucosal epithelial cell and most preferably a buccal epithelial cell (col. 4, lines 20-50).

At column 8, lines 34-52, Sundstrom teaches that in a preferred embodiment, a substrate for mammalian transglutaminases can inhibit the binding of one or more mammalian transglutaminases to purified Hwp1 protein or a polypeptide comprising the amino acid sequence of Fig. 1, wherein said polypeptide is itself capable of acting as a substrate for mammalian transglutaminases. In addition, microbial interaction with a mammalian host can

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include attachment or adhesion to the host cell surface, invasion of host cells, and elaboration of toxins, for example. The involvement of pathogenic mechanisms or virulence factors of the microorganisms can result in beneficial effects to the mammalian host.

In Example 7, cols. 19 and 20, Sundstrom teaches a pharmaceutical composition containing polypeptide substrates for mammalian transglutaminases in powder form, along with pharmaceutical carriers, which could also be prepared as a liquid preparation suitable for injection, for the purpose of inhibiting transglutaminase-mediated microbial interaction with a mammalian host. The peptides may be delivered by any convenient means that will result in the delivery to the subject of an effective amount to inhibit transglutaminase-mediated microbial interaction with a mammalian host. The amount administered will depend on the activity of the particular compound administered, which may readily be determined by one skilled in the art.

It is the position of the Examiner that the prior art teaches the generic concept of the use of isoleucine to inhibit microbial infection and interaction with the mammalian host, since isoleucine is within the group of polypeptides disclosed at columns 10 and 16. One of ordinary skill would recognize that since isoleucine is taught to inhibit microbial interaction, it also teaches the prevention of the adherence of microbes, as desired by the applicant. Hence, no significant distinction is observed between the prior art and the instant invention.

With regards to the instantly claimed amounts and ranges of isoleucine employed, it is deemed obvious to one of ordinary skill in the art that suitable

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amounts and ranges could be determined through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
December 01, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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